

Appendix A

Claim Amendments

1. (Currently amended) A compliance monitor for a drug delivery device for administering a drug, comprising:  
[[;]]  
a switch actuatable by a user on delivering a dose from the device;  
a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and  
a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated.
2. (Currently amended) [[A]] The compliance monitor according to claim 1, which does not affect the normal operation of the drug delivery device.
3. (Currently amended) [[A]] The compliance monitor according to claim 1 [[or 2]], which is removably attachable to the drug delivery device.

4. (Currently amended) **[[A]]** The compliance monitor according to ~~any preceding~~ claim 1, comprising a clock coupled to the processor and in which the time of actuation of the switch is recorded.
  
5. (Currently amended) **[[A]]** The compliance monitor according to ~~any preceding~~ claim 1, wherein the proper positioning of the drug delivery device is **[[being]]** positioning in contact with or relative to the user's mouth, nose or skin, ~~as appropriate for administration of the drug.~~
  
6. (Currently amended) **[[A]]** The compliance monitor according to ~~any preceding~~ claim 1, wherein the drug delivery device is **[[being]]** for topical administration of the drug.
  
7. (Currently amended) **[[A]]** The compliance monitor according to ~~any preceding~~ claim 1, wherein the drug delivery device is **[[being]]** for oral administration of the drug, ~~preferably by inhalation.~~

8. (Currently amended) **[[A]]** The compliance monitor according to ~~any preceding~~ claim 1, wherein the drug delivery device is **[[being]]** an inhaler operated by the user depressing a pressurized ~~pressurised~~ canister containing the drug, and ~~in which~~ wherein the switch is a pressure-operated switch actuatable as the user depresses the canister.
  
9. (Currently amended) **[[A]]** The compliance monitor according to ~~any preceding~~ claim 1, wherein the drug delivery device is selected from the group consisting of **[[being]]** a dry powder inhaler, a pressurized ~~pressurised~~ metered dose inhaler and **[[or]]** a nebuliser.
  
10. (Currently amended) **[[A]]** The compliance monitor according to ~~any preceding~~ claim 1, in which the sensor is a temperature sensor for sensing body temperature, ~~for example mouth temperature.~~
  
11. (Currently amended) **[[A]]** The compliance monitor according to ~~any preceding~~ claim 1, in which the

sensor is a light sensor for sensing when the sensor is covered, ~~for example by the mouth.~~

12. (Currently amended) **[[A]]** The compliance monitor according to ~~any preceding~~ claim 1, in which the sensor is a conductivity sensor for sensing body conductivity, ~~for example mouth conductivity.~~

13. (Currently amended) **[[A]]** The compliance monitor according to ~~any preceding~~ claim 1, in which a change in an output of the sensor characteristic of correct use of the drug delivery device is used to determine whether the device was properly positioned when the dose was delivered.

14. (Currently amended) **[[A]]** The compliance monitor according to ~~any preceding~~ claim 1, further comprising an output for downloading data to a docking station or a computer.

15. (Currently amended) **[[A]]** The compliance monitor according to ~~any preceding~~ claim 1, in which the data comprises a compliance record of use of the drug

delivery device, including a record of whether the sensor output indicates that the device was properly positioned on each occasion that a dose has been delivered.

16. (Currently amended) A docking station for use with a compliance monitor as defined in claim 1 ~~any of claims 1 to 15.~~

17. (Currently amended) A computer-readable medium carrying a computer program for programming a general purpose computer to receive and process data downloaded from a compliance monitor as defined in claim 1 ~~any of claims 1 to 15.~~

18. (Currently amended) A drug delivery device comprising a compliance monitor as defined in claim 1 ~~any of claims 1 to 15.~~

19. (Currently amended) A method of using a compliance monitor to monitor use of a drug delivery device for administration of a drug, comprising the steps of:  
[[;]]

determining when a user operates the device to deliver a dose of the drug;

sensing whether the device is properly positioned in contact with or relative to the user's body when the dose is delivered; and

recording for each operation of the device whether or not the device was properly positioned.

20. (Currently amended) **[[A]]** The method according to claim 19, further comprising the step of determining and recording the time of each operation of the device.

21. (Currently amended) **[[A]]** The method according to claim 19 **[[or 20]]**, in which the drug delivery device is for oral administration of the drug and proper positioning of the device is proper positioning in the user's mouth.

22. (Currently amended) **[[A]]** The method according to claim 19, ~~20 or 21~~, further comprising the step of downloading recorded data from the compliance monitor to a docking station or a computer to allow a

compliance record to be reviewed,~~for example by a~~  
~~medical practitioner.~~

23. - 24. (Canceled)

25. (New) The compliance monitor according to claim 7,  
wherein the drug delivery device is for oral  
administration by inhalation.